K093944 (pg 1/3)

Medacta International

JAN 21 2010

Special 510(k) Summary

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Date Prepared: December 16, 2009

DEVICE INFORMATION

Trade/Proprietary Name: Medacta Total Hip Prosthesis – AMIStem H, Quadra S and Quadra H femoral stems

Common/Classification Name: Hip Joint, metal/ceramic/polymer, semi-constrained, cemented or nonporous uncemented prosthesis

Classification: Class II, 21 CFR 888.3353
Product Code: LZO, MEH

Predicate Device: Medacta Total Hip Prosthesis – Quadra S femoral stems, K072857, cleared on February 4, 2008

Product Description:
The modifications to the original Medacta Total Hip Prosthesis system are a line extension to include the AMIStem H femoral stems. As well as, Quadra S short neck and Quadra H short neck femoral stems. The AMIStem H has the same application of a hydroxyapatite (HA) coating as the Quadra H stems cleared in 510(k) K082792. AMIStem H femoral stems are based on the design of the Quadra S femoral stems in the original submission as well as the Quadra H femoral stems cleared in 510(k) K082792. The AMIStem H differs from Quadra H and Quadra S by a decreased length of 15% and a

reduced shoulder. The Quadra H short neck femoral stems are the same design femoral stems as the Quadra S femoral stems in the original submission but with the application of a hydroxyapatite coating.

The Quadra S short neck femoral stems are the same as those in the original submission except they are offered in larger sizes. The Quadra H short neck femoral stems are the same as those in submission K082792 except they are offered in larger sizes.

Indications for Use:
The Medacta Total Hip Prosthesis System is intended for cementless use in total or partial hip arthroplasty and in primary or revision surgery.

Hip replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia.
- Avascular necrosis of the femoral head.
- Acute traumatic fracture of the femoral head or neck.
- Failure of previous hip surgery, joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

Comparison to Predicate Device:
The indications for use for the modified system remain the same as the original 510(k), K072857.

The AMIStem H femoral stems and Quadra H short neck femoral stems are manufactured from a titanium alloy, according to ISO 5832-11, 1994, Implants for surgery – Metallic materials – part 11: Wrought titanium 6-aluminum 7-niobium alloy, the same as the Quadra S femoral stems in the original submission. They are sandblasted and the neck has a mirror polished finish, the same as the Quadra S. They have a standard 12/14 taper for connection to the ball head, the same as the Quadra S. The AMIStem H femoral stems and Quadra H short neck femoral stems differ from the Quadra S in that they have a hydroxyapatite coating applied to the distal portion of the femoral stems.

The Quadra S short neck femoral stems are manufactured from a titanium alloy, according to ISO 5832-11, 1994, Implants for surgery – Metallic materials – part 11: Wrought titanium 6-aluminum 7-niobium alloy, the same as the Quadra S femoral stems in the original submission. They are sandblasted and the neck has a mirror polished finish, the same as the Quadra S. They have a standard 12/14 taper for connection to the ball head, the same as the Quadra S.

The AMIStem H femoral stems are available in two versions, standard and lateralized stems; there are no short neck versions. The sizes are the same as Quadra S femoral stems except size 10 standard is not available and size 8 lateralized is available. The AMIStem H differs from Quadra S and Quadra H by a decreased length of 15% and a reduced shoulder. Two different caput-collum-diaphyseal angles (CCD) are available, 135° for the standard version and 127° for the lateralized version, same as the Quadra S and Quadra H.

The Quadra S and Quadra H short neck femoral stems are available in two versions, standard and lateralized stems. The Quadra S and Quadra H short neck line is extended to include larger standard sizes 4 to10 and larger lateralized sizes 4 to 7. The Quadra S short neck is identical to the Quadra S short neck femoral stems in the original submission. The Quadra H short neck is identical to the Quadra H short neck femoral stems.

The AMIStem H femoral stems and Quadra S and H short neck femoral stems work with the same range of ball heads cleared under the original Medacta Total Prosthesis System, K072857, and subsequent submissions for the MectaCer Ceramic ball heads, K073337, and for additional CoCrMo ball head sizes, K080885. The AMIStem H femoral stems and these ball heads work with Ortho Development's Triplus® acetabular cups and liners as well as Medacta's Versafitcup® Double Mobility acetabular cups and liners. They can also be used with Medacta CoCrMo femoral ball heads of sizes 22 and 28 and Ortho Development's Pivot Bipolar heads. The same is true for the Quadra S and H short neck femoral stems. These system compatibilities are the same as the original devices, Quadra S femoral stems.

Performance Testing:
No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act.

Risk analysis was conducted on the impact of these changes and appropriate design verification and validation was conducted under the company's design controls.

Conclusion:
The results from design controls and the information provided in this submission support the conclusion that the Medacta Total Hip Prosthesis System - AMIStem H femoral stems and Quadra S and H short neck femoral stems are substantially equivalent to their predicate, Medacta Total Hip Prosthesis System – Quadra S femoral stems with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Re: K093944
Trade/Device Name: Medacta Total Hip Prosthesis – AMIStem H, Quadra S and Quadra H femoral stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH
Dated: December 16, 2009
Received: December 22, 2009

Dear Ms. Neely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

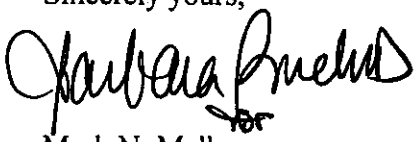
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known): K093944 (pg 1/1)

Device Name: Medacta Total Hip Prosthesis System – AMIStem H, Quadra S, Quadra H

Indications For Use:

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- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia.
- Avascular necrosis of the femoral head.
- Acute traumatic fracture of the femoral head or neck.
- Failure of previous hip surgery, joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

Prescription Use __X__ AND/OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093944